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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,846	02/13/2002	John N. Feder	D0079 NP	9057

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EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/075,846	FEDER ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-27 and 30-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20, 21, 23, 25, 27 and 30-36* is/are rejected.

7)☒ Claim(s) *22,24 and 26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/10/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's response and amendment filed on 03 June 2004 is acknowledged and entered. Following the amendment, claims 28, 29, and 37-40 are canceled, claims 20 and 30 are amended.

Currently, claims 20-27 and 30-36 are pending and under consideration.

The finality of the rejection of the last Office action is withdrawn in view of new grounds of rejection, which are set forth below.

Withdrawal of Objections and Rejections:

All objections and rejections of claims 28, 29, and 37-40 are moot as the applicant has canceled the claim.

The scope rejection of claims 20 and 30-36 under 35 U.S.C. 112, first paragraph, made in the last Office Action mailed on 17 May 2004 is withdrawn in view applicants amendment.

The rejection of claims 20-27 and 30-36 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view applicants amendment.

Objections and Rejections under 35 U.S.C. §101 and §112:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 20, 21, 23, 25, 27 and 30-36 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a credible, substantial, specific, or well-established utility.

Claims 20, 21, 23, 25 and 27 encompass or are directed to an isolated nucleic acid *encoding* a human polypeptide of SEQ ID NO:4, or a specific portion of SEQ ID NO:4. Said polypeptide is a putative glycine receptor α4 subunit splice variant, and designated HGRA4sv.

As addressed in the Office Action mailed on 17 May 2004, the utility of the presently claimed nucleic acid is established based on the disclosure of the prior art reference by Rappold-

Hoerbrand (WO 00/58461), wherein a gene positively associated with ataxia is disclosed, and the Rappold-Hoerbrand's ataxia protein (SEQ ID NO:2) encoded by said gene is 100% identical to applicants HGRA4, and represents a splice variant of the HGRA4sv of the present invention.

The specific and substantial utility established by the Rappold-Hoerbrand reference is a diagnosis use based on that the gene is responsible for disorders relating to ataxia as the chromosomal breakpoint of the patient having ataxia is found to reside within the genomic locus of said gene, which is demonstrated by restriction enzyme analysis of the ataxia cDNA, wherein a band shift was observed in the patient, but not in healthy controls (page 5, the third and fourth paragraphs). Therefore, the diagnosis use of the gene depends upon the specific pattern generated by restriction enzyme analysis. Such a specific pattern of a nucleic acid is determined by the unique sequence of the nucleic acid. A limitation of "an isolated polynucleotide *encoding* a polypeptide" in the present claims (parts (a)-(c) of claim 20, for example) reads on the disclosed specific polynucleotide of SEQ ID NO:3, which encodes the polypeptide of SEQ ID NO:4, as well as polynucleotides with all possible degeneracy and encoding SEQ ID NO:4. The later would be highly likely to generate different patterns from that of the prior art when subjected to the restriction enzyme digestion, which would not reflect the association to said disorder. As such, those polynucleotides with the sequence degeneracy would not be suitable for the diagnosis use established by the prior art. Further, neither the prior art nor the present specification teaches specifically the use of those polynucleotides for the purpose of diagnosis or any other purpose. Thus, there was no immediately apparent or "real world" utility for those polynucleotides, and the claimed invention is incomplete as of the filing date. One may argue that the polynucleotides with the degenerate sequences can be used for the production of the polypeptide. However, as of the filing date of the present application, no specific and substantial utility for the polypeptide was established or disclosed by the instant specification. Until a specific and substantial utility can be attributed to the HGRA4sv polypeptide, use of a nucleic acid for the production of the protein is not considered by the Patent Office to be a specific or substantial utility, as such use could be asserted for *any* cDNA.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20, 21, 23, 25, 27 and 30-36 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial or credible utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion:

Claims 22, 24 and 26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
6/29/04